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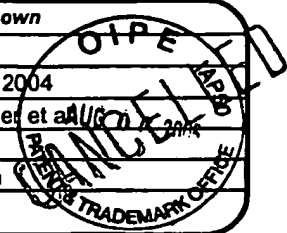
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

|                        |                      |
|------------------------|----------------------|
| Application Number     | 10/759,573           |
| Filing Date            | January 16, 2004     |
| First Named Inventor   | Claude Singer et al. |
| Art Unit               | 1615                 |
| Examiner Name          | Simon J. Oh          |
| Attorney Docket Number | 1662/52804           |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. 1 | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant<br>of Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|------------------------|---------------|--------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|
|                        |               | Number - Kind Code <sup>2</sup> (if known) |                                |                                                    |                                                                                 |
| SO                     |               | 5,095,148                                  | March 10, 1992                 | Mettler et. al.                                    |                                                                                 |
|                        |               | 5,510,381                                  | April 23, 1996                 | A.C. Pande                                         |                                                                                 |
|                        |               | 5,149,870                                  | September 22,<br>1992          | Mettler et al.                                     |                                                                                 |
|                        |               | 5,136,091                                  | August 4, 1992                 | Mettler et al.                                     |                                                                                 |
|                        |               | 5,130,455                                  | July 14, 1992                  | Mettler et al.                                     |                                                                                 |
|                        |               | 5,095,148                                  | March 10, 1992                 | Mettler et al.                                     |                                                                                 |
|                        |               | 6,765,114                                  | July 20, 2004                  | Gizur et al.                                       |                                                                                 |
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|                        |               | 6,294,690                                  | September 25,<br>2001          | Deering et al.                                     |                                                                                 |
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**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. 1 | Foreign Patent<br>Document                                                             | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures<br>Appear | T <sup>3</sup><br>Yes<br>(Abs.) |
|------------------------|---------------|----------------------------------------------------------------------------------------|--------------------------------|-------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------|
|                        |               | Country Code <sup>2</sup> - Number <sup>4</sup> -<br>Kind Code <sup>5</sup> (if known) |                                |                                                       |                                                                                    |                                 |
| SO                     |               | DE 24 80 891                                                                           | July 1, 1976                   | Satzinger et al.                                      |                                                                                    |                                 |
|                        |               | EP 0 458 751 A1                                                                        | Nov. 27, 1991                  | Cherukuri et al.                                      |                                                                                    |                                 |
|                        |               | WO 97/33858                                                                            | Sept. 18, 1997                 | Horwell et al.                                        |                                                                                    |                                 |
|                        |               | GB 898 692                                                                             | June 14, 1962                  | Wamer Lambert                                         |                                                                                    |                                 |
|                        |               | WO 04/46108                                                                            | June 3, 2004                   | Kuppuswamy et al.                                     |                                                                                    |                                 |
|                        |               | WO 00/01660                                                                            | January 13, 2000               | Palocchi et al.                                       |                                                                                    |                                 |
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|                        |               | WO 99/18063                                                                            | April 15, 1999                 | Deering et al.                                        |                                                                                    |                                 |
|                        |               | WO 96/36328                                                                            | July 22, 1999                  | Pande                                                 |                                                                                    |                                 |
|                        |               | WO 92/14443                                                                            | September 3, 1992              | Chaturvedi et al.                                     |                                                                                    |                                 |

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|-----------------------|----------|--------------------|---------|
| Examiner<br>Signature | Simon Oh | Date<br>Considered | 9/22/05 |
|-----------------------|----------|--------------------|---------|

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| Substitute for form 1449B/PTO                                                                     |   | <b>Complete if Known</b> |                      |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   | Application Number       | 10/759,573           |
|                                                                                                   |   | Filing Date              | January 16, 2004     |
|                                                                                                   |   | First Named Inventor     | Claude Singer et al. |
|                                                                                                   |   | Art Unit                 | 1615                 |
|                                                                                                   |   | Examiner Name            | Simon J. Oh          |
|                                                                                                   |   | Attorney Docket Number   | 1662/52804           |
| Sheet                                                                                             | 2 | of                       | 3                    |

| NON PATENT LITERATURE DOCUMENTS |                       |                                                                                                                                                                                                                                                                                                                                                                         |                |
|---------------------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Examiner Initials *             | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                                                                                                         | T <sup>2</sup> |
| SO                              |                       | Zour et al. "Stability studies of gabapentin in aqueous solutions" <i>Pharmaceutical Research</i> , Vol. 9, No. 5, 1992 pages 595-600                                                                                                                                                                                                                                   |                |
|                                 |                       | USP Monograph for Gabapentin<br><i>Pharmacopeial Forum</i> , Vol. 25, No. 5, Sept.-Oct. 1999, pages 8711-8717                                                                                                                                                                                                                                                           |                |
|                                 |                       | Holder, R.W. et al., "Geminate-Substituted Cyclopentadienes. 1. Synthesis of 5,5-Dialkylcyclopentadienes via 4,4-Dialkylcyclopent-2-en-1-ones", <i>J. Org. Chem.</i> 1982, Vol. 47, pages 1445-1451.                                                                                                                                                                    |                |
|                                 |                       | Thorpe et al.; paper entitled, "The Formation and Reactions of Imino Compounds: Part XVIII. The Condensation of cycloHexanones with Cyanoacetamide Involving the Displacement of an Alkyl Group. <i>J. Chem. Soc.</i> 1913, pages 1586-1600.                                                                                                                            |                |
|                                 |                       | Vogel, A.I., paper entitled "Physical Properties and Chemical Constitution: Part II. Esters of $\gamma$ -Substituted Glutaric Acids. <i>J. Chem. Soc.</i> , 1934, pages 1758-1765                                                                                                                                                                                       |                |
|                                 |                       | Griffiths et al., "Novel Synthesis of Gabapentin via Addition of Hydrocyanic Acid to Cyclohexylidenemalonate or Cyano(cyclohexylidene) acetate," <i>Helvetica Chimica Acta</i> , 74, 309 (1991)                                                                                                                                                                         |                |
|                                 |                       | Kearney et al., "The Effect of Cyclodextrins on the Rate of Intramolecular Lactamization of Gabapentin in Aqueous Solution," <i>International Journal of Pharmaceutics</i> , 78, 25-34 (1992).                                                                                                                                                                          |                |
|                                 |                       | Notice of Opposition to A European Patent, No. 1 289 364 of Teva Pharmaceutical Industries Ltd., Opponent: Hikal Limited, 10 December 2003, European Patent Bulletin, pp. 1-4; and Statement of Grounds for Opposition, pp. 1-16.                                                                                                                                       |                |
|                                 |                       | Arrow Generics Limited and Teva Pharmaceutical Industries Limited, Amended Grounds of Invalidity, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 00951, 16 March 2004, pp. 1-3.                                                                                                                                                         |                |
|                                 |                       | Teva Pharmaceutical Industries Limited and Generics (UK) Limited, Defence and Counterclaim, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 03383, 17 December 2004, pp. 1-2 and pp. 1-3.                                                                                                                                                |                |
|                                 |                       | Teva Pharmaceutical Industries Ltd. v. Hikal Group Ltd., Civil Action No. 1:05-cv-00691 (ESH), In the United States District Court for the District of Columbia, Answer, Affirmative Defenses, Counterclaim and Jury Trial Demand of Defendants Apotex Corp. and Apotex Inc., May 16, 2005, pp. 1-59.                                                                   |                |
|                                 |                       | Teva Pharmaceutical Industries Limited and Generics (UK) Limited, Grounds of Invalidity, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 03383, 17 December 2004, pp. 1-3.                                                                                                                                                               |                |
|                                 |                       | Request for Examination Under Section 35(1) of the Act and Request for Advanced Examination Under Section 28 of the Rules in Teva Pharmaceutical Industries' Canadian Patent Application No. 2,411,787, to Commissioner of Patents (Canada) by Kirby Eades Gale Baker on May 27, 2005, pp. 2-14, (incl. Appendix A, 12 pages, Appendix B, 1 page, Appendix C, 5 pages.) |                |
|                                 |                       | Complaint, of Teva Pharmaceutical Industries Ltd. against Hexal AG and Salutas Pharma GmbH, Regional Court Dusseldorf, 4 <sup>th</sup> Civil Chamber, October 20, 2003, pp. 10.                                                                                                                                                                                         |                |

Simon Oh 9/22/03

|    |  |                                                                                                                                                                                                                                                     |  |
|----|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Se |  | Complaint, of Teva Pharmaceutical Industries Ltd. against ratiopharm GmbH and Merckle GmbH, Regional Court Dusseldorf, 4 <sup>th</sup> Civil Chamber, October 20, 2003, pp. 10.                                                                     |  |
|    |  | Complaint, of Teva Pharmaceutical Industries Ltd. against STADapharm GmbH and STADA Arzneimittel AG, Regional Court Dusseldorf, 4 <sup>th</sup> Civil Chamber, October 20, 2003, pp. 10.                                                            |  |
|    |  | Complaint, of Teva Pharmaceutical Industries Ltd. against Zambon Group SpA (Italy) and Zambon GmbH, Regional Court Dusseldorf, 4 <sup>th</sup> Civil Chamber, October 20, 2003, pp. 10.                                                             |  |
|    |  | Reply and Counterclaim Brief of Teva Pharmaceutical Industries Limited, and Zambon Group SpA, Court of Milano, Section specialized in intellectual and industrial property matters, Case No. 77571/03, February 7, 2004, pp. 1-14.                  |  |
|    |  | Writ of Summons, Court of Milan, Zambon Group SpA and Teva Pharmaceutical Industries Ltd., Milan, December 9, 2003, pp. 1-21.                                                                                                                       |  |
|    |  | Brief of Reply for the Plaintiff, Court of Milano, Section Specialized in Industrial Right I.J. Dr. Migliaccio In the Lawsuit No. 77571/02 brought by Zambon Group SpA against Teva Pharmaceutical Industries Ltd., Milan, June 15, 2004, pp. 1-15. |  |
| ✓  |  |                                                                                                                                                                                                                                                     |  |

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|-----------------------|-----------------|--------------------|---------|
| Examiner<br>Signature | <i>Simon Au</i> | Date<br>Considered | 9/22/05 |
|-----------------------|-----------------|--------------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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